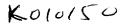




SPECIAL 510(K) NOTIFICATION OF A NEW DEVICE

FEB - 9 2001

SPECIAL 510(K) 64 CHANNEL EEG JANUARY 16, 2001 PAGE 1 of 1



510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR § 807.92.

Name:

Cameron Mahon

Director of R & D

Address:

XLTEK

2568 Bristol Circle

Oakville, Ontario

Canada, L6H 5S1

Telephone:

(905) 829-5300

Fax:

(905) 829-5304

E-mail:

research@xltek.com

Common Names:

64 Channel EEG

Classification Name:

Electroencephalograph

Predicate Devices:

NeuroWorks [FDA 510(k) K980214]

Description:

The 64 Channel EEG is a digital electroencephalograph

Substantial Equivalence:

The 64 Channel EEG is substantially equivalent to the NeuroWorks

[FDA 510(k) K980214]

Indications for Use:

The 64 Channel EEG is intended to be used as an

electroencephalograph: to acquire, display store, and archive

electroencephalographic signals..



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

FEB - 9 2001

Ms. Sonja Markez Regulatory Manager Excel Tech, Ltd. 2568 Bristol Circle Oakville, Ontario Canada L6H 5S1

Re:

K010150

Trade Name: 64 Channel EEG

Regulatory Class: II Product Code: GWQ Dated: January 16, 2001 Received: January 17, 2001

Dear Ms. Markez:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriamil Provost For Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and Neurological Devices Office of Device Evaluation Center for Devices and Radiological Health

Enclosure



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64 CHANNEL EEG
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Statement of Indications for Use

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510(k) Number (if known):	K010130
Device Name:	NeuroWorks
Indications for Use:	The Neuro Works EEG is intended to be used as an electroencephalograph: to acquire, store, and archive electroencephalographic signals.
(PLEASE DO NOT WRITE PAGE IF NEEDED)	BELOW THIS LINE - CONTINUE ON ANOTHER
Concurrence of	CDRH, Office of Device Evaluation (ODE)
Prescription Use	OR Over-The Counter Use
<u>Mur</u> (Divisi Division and Ne	(Optional Format 1-2-96) on Sign-Off) on of General, Restorative curological Devices Number K0/0/50